

REMARKS

Claims 27 and 28 are pending in the present application.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Rejection of Claims 27-28 under 35 U.S.C. § 112, First Paragraph

Claims 27-28 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Office Action states:

Applicants appear to argue that by "identifying characteristics" is intended all of the growth and morphological characteristics that are disclosed for example on page 5, line 24 - page 6, line 3 or alternatively disclosed in US 3,937,654. Firstly, neither the instant specification nor US 3,937,654 provide "the identifying characteristics" of ATCC 20334. Secondly, the instant disclosure provides no characteristics specific to ATCC 20334. Therefore, it is unclear what is intended by "identifying characteristics". In other words, what characteristics are considered "identifying". If applicants intend that by "identifying characteristics" they intend the growth and morphological characteristics outlined on (see e.g., page 5, line 24 - page 6, line 3), this is not encompassed by the instantly recited language. Rather an "identifying characteristic" can be a broad and diverse designation for which the instant specification has no disclosure.

This rejection is respectfully traversed for the reasons of record and the reasons asserted below.

In the current Office Action, the Office repeats many of the arguments made in the Office Action of July 26, 2004. Those arguments were addressed in the October 27, 2004 Amendment and for the most part will not be repeated here.

The Office provides that it is unclear what is intended by "identifying characteristics". The term "identifying characteristics" is well known in the art and refers to the growth and morphological characteristics of a species or genus of a microorganism. It has been used in numerous issued U.S. patents. See, for example, U.S. Patent Nos. 4,292,406, 5,298,245, 5,330,547, 5,427,786, and 6,110,726.

The Office states "neither the instant specification nor US 3,937,654 provide 'the identifying characteristics' of ATCC 20334." Applicants disagree with this assertion. With regard to the instant specification, Applicants state on page 5, line 24 to page 6, lines 6, of the specification:

In a specific embodiment, the host cells of the present invention are of the species *Fusarium graminearum* which is characterized by the following features. Conidia: Microconidia are absent. Macroconidia are distinctly septate, thick walled, straight to moderately sickle-shaped, unequally curved with the ventral surface almost straight and a smoothly arched dorsal surface. The basal cell is distinctly foot-shaped. The apical cell is cone-shaped or constricted as a snout. Conidiophores: unbranched and branched monophialides. Chlamydospores: are generally very slow to form in culture; when they do occur, they most often form in the macroconidia but may also form in the mycelium. Colony morphology: on PDA, growth is rapid with dense aerial mycelium that may almost fill the tube and is frequently yellow to tan with the margins white to carmine red. Red-brown to orange sporodochia, if present, are sparse, often appearing only when the cultures are more than 30 days old. The undersurface is usually carmine red. This fungus produces the most cylindrical (dorsal and ventral surfaces parallel) macroconidia of any species of the section *Discolor*.

In a most specific embodiment, the *Fusarium graminearum* is *Fusarium graminearum* Schwabe IMI 145425, deposited with the American Type Culture Collection and assigned the number ATCC 20334 (U.S. Patent No. 4,041,189), as well as derivatives and mutants which are similarly non-toxic, non-toxigenic, and non-pathogenic, e.g. those taught in U.S. Patent No. 4,041,189.

Strain ATCC 20334 (= strain NRRL 30747 = IMI 145425) is also described in the ATCC Catalog (pertinent pages were provided in the Amendment of October 27, 2004). The Catalog references U.S. Patent No. 3,937,654 (issued February 10, 1976), which discloses the morphological and growth characteristics of *Fusarium* strain ATCC 20334. Column 2, lines 5-7, of the '654 patent states: "Our new strain of *Fusarium graminearum* Schwabe, I.M.I 145425, is non-pathogenic to wheat. It has the following morphological characteristics". Column 2, lines 9-44, of the '654 patent discloses growth conditions and media, rate of growth, character of growth, and conidia for *Fusarium graminearum* Schwabe IMI 145425. For example, the '654 patent describes conidia of *Fusarium graminearum* Schwabe IMI 145425 as follows:

Microconidia not produced by this organism. Macroconidia produced from single lateral phialides or multibranched conidiophores with short phialides. In older cultures the conidiophores aggregate to form sporodochia, particularly on CDA. The conidia vary from falcate to curved fusoid dorsi-ventral, septation varying from 3 to 5, commonly 5 in younger cultures. Spore size varies from 25 - 50 μ x 2.5 μ - 4.0 μ . The foot cell is often pedicellate, particularly in the longer 5 septate spores. Swollen cells occur in the mycelium and occasionally chlamydospores occur intercalary, singly or in chains.

Consequently, the instant specification and US 3,937,654 provide "the identifying characteristics" of ATCC 20334.

Applicants would like to emphasize that the identifying characteristics associated with strain ATCC 20334 have not changed because the species name has changed. There is no diversity of "identifying characteristics" associated with strain ATCC 20334. It is well known in the art that a strain may be reclassified taxonomically as new strains are isolated and differences between the isolates are discovered. Moreover, new methodologies may be developed that enhance the ability to discern differences between strains of presumptively the same genus and species. For example, Yoder and Christenson, 1998, *Fungal Genetics and Biology* 23: 68-80 (see attachment), describe the use of species-specific primers to resolve members of *Fusarium* Section *Fusarium*. O'Donnell *et al.*, 1998, *Fungal Genetics and Biology* 23: 57-67 (see attachment), disclose methodologies for obtaining molecular phylogenetic, morphological, and mycotoxin data for strain ATCC 20334. However, the morphological and growth identifying characteristics for a strain such as ATCC 20334 do not change. The identifying characteristics of strain ATCC 20334 have been, and probably will continue to be, added to, allowing increasingly subtle differentiation because of the implementation of new molecular techniques, but the original morphological and growth characteristics of the ATCC 20334 strain remain unaltered. This is true whatever new name, *forma specialis etc.*, may be applied to the strain – it will always retain its original morphological and growth identifying characteristics.

One of ordinary skill in the art equipped with the identifying growth and morphological characteristics described in the '654 patent for strain ATCC 20334 and in the instant specification would, therefore, be able to identify a host cell having the identifying growth and morphological characteristics of the non-toxic, non-toxigenic, non-pathogenic *Fusarium venenatum* host cell of ATCC 20334.

Applicants submit that the specification in combination with the prior art does reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

For the foregoing reasons, Applicants submit that this rejection under 35 U.S.C. § 112 has been overcome and respectfully request withdrawal of the rejection.

II. The Rejection of Claims 27-28 under 35 U.S.C. § 112, Second Paragraph

Claims 27 and 28 stand rejected under 35 U.S.C. § 112, second paragraph, as being vague and indefinite in that the phrase "the identifying characteristics" is unclear. The Office Action states:

It is unclear how to distinguish *Fusarium venenatum* cells having "the identifying characteristics". The specification does not define "the identifying characteristics" that are to be used to identify the recited host cells nor does

the prior art have a single excepted definition for "identifying characteristics".
As "identifying characteristics" is a relative term, the metes and bounds of the host cell unknown.

This rejection is respectfully traversed.

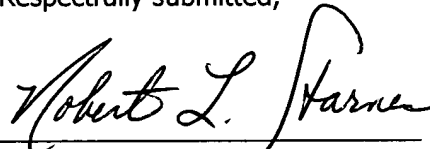
Based on the arguments provided in Section I, the metes and bounds of "the identifying characteristics" are clear.

For the foregoing reason, Applicants submit that this rejection under 35 U.S.C. § 112 has been overcome and respectfully request withdrawal of the rejection.

III. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

A handwritten signature in black ink, reading "Robert L. Starnes". The signature is written in a cursive style with a large, looping "S" at the end.

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